IX. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

December 8, 2000 JAN - 4 2001

1. Submission Applicant & Correspondent:

Name:	Osteotech, Inc.
Address:	51 James Way Eatontown, NJ 07724
Phone No.:	(732) 544-6231
Contact Person:	Kim Thurman

2. Name of Device:

Trade/Proprietary/Model Name:	VBR™
Common or Usual Name:	Vertebral Body Replacement Device
Classification Name:	Spinal Vertebral Body Replacement Device

3. Devices to Which New Device is Substantially Equivalent:

The VBR™ is substantially equivalent, for the purpose of this 510(k), to the following predicate devices.

Trade/Proprietary/Model Name	Manufacturer
OEC/Rezaian Spinal Fixator	Orthopedic Equipment Co, Inc.
DePuy Acromed Stackable	DePuy AcroMed, Inc.

4. Device Description:
The VBR™ is a cylindrically shaped implantable device with an open hollow core throughout its long axis. It is distractible and retractable by means of rotating the center component. A plurality of holes is built in the wall of the VBR™, transverse to the longitudinal axis. On the end pieces, the first ring of holes closest to the center component are threaded to accept set screws, which, when tightened, serve to prevent further movement (distraction, retraction, or turning) of the VBR™ once the desired height has been achieved. The holes and the hollow core also allow the use of grafting materials to help achieve a solid fusion. A ring of small spikes or teeth on the device serves to grip the endplates of the adjacent vertebrae for resisting expulsion.

The VBR™ is manufactured from titanium alloy (Ti6Al4V) which conforms to ASTM F136 and ISO 5832/3 standards.

The VBR™ is available in various sizes to better match patients' anatomical requirements.

The VBR™ implants are for single patient use and are offered for sale non-sterile. They must be sterilized prior to use.

5. Intended Use/Indications

The VBR™ is vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture).

The VBR™ is intended to be used with supplemental internal spinal fixation systems that are cleared by FDA for use in the thoracic and/or lumber spine. Such systems include posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems.

The use of bone grafting material with the VBR™ is optional.

6. Technical Comparison
The VBR™ is similar to the Rezaian Spinal Fixator in terms of design and technical characteristics. Both devices are cylindrically shaped implantable devices with an open hollow core throughout their long axis. Both of them are distractible and retractable by means of rotating the center component. Both contain a plurality of holes in the walls, which together with the hollow core allow the use of grafting materials to help promote a solid fusion. Both devices have a ring of small spikes which serves to grip the endplates of the adjacent vertebrae for resisting expulsion. They are also similar in dimensions. The VBR™ is also similar to the DePuy Acromed Stackable Cage System with respect to certain technical characteristics.

7. Performance Data
Mechanical testing and a clinical study have been conducted on the VBR™ to show equivalence to predicate devices and demonstrate its capability to withstand *in vivo* loads.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 2001

Ms. Kim Thurman
Regulatory Affairs Associate
Osteotech, Inc.
51 James Way
Eatontown, New Jersey 07724

Re: K003155
Trade Name: VBR™
Regulatory Class: II
Product Code: MQP
Dated: December 8, 2000
Received: December 11, 2000

Dear Ms. Thurman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

L. Indications for Use Statement

510(k) Number (if known): K003155
Device Name: VBR™

Indications for Use:

The VBR™ is vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture).

The VBR™ is intended to be used with supplemental internal spinal fixation systems that are cleared by FDA for use in the thoracic and/or lumber spine. Such systems include posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems.

The use of bone grafting material with the VBR™ is optional.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General Restorative Devi
510(k) Number K003155